K002706

MAR 1 6 2001

# 510(k) Summary

| | |
|---|---|
| **Introduction** | According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence |
| **Submitter name, address, contact** | Roche Diagnostics Corporation<br>9115 Hague Rd<br>Indianapolis IN 46250<br>(317) 576-3544<br><br>Contact person: Kay A. Taylor<br><br>Date prepared: March 13, 2001 |
| **Predicate device** | The Roche Diagnostics Tina-quant® D-Dimer Test System is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Diagnostica Stago Asserachrom D-Di Kit (K862156). |
| **Device name** | Proprietary name: Roche Diagnostics Tina-quant® D-Dimer Test System<br><br>Common name: D-Dimer Test System<br><br>Classification name: Fibrinogen/Fibrin Degradation Products Assay |
| **Device description** | The Tina-quant® D-Dimer Test System is based on a particle enhanced immunoturbidimetric assay. Human D-Dimer agglutinates with latex particles coated with anti-D-Dimer antibodies. The precipate is determined turbidimetrically. |

## 510(k) Summary, continued

**Intended use**

For the in vitro quantitative determination of fibrin degradation products.

**Indication for use**

Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation.

**Substantial equivalence**

The Tina-quant® D-Dimer Test System is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the American Bioproducts Asserachrom D-Di Kit (K862156).

**Substantial equivalence-similarities**

The following table compares the Tina-quant D-Dimer Test System with the predicate device.

| Feature | Tina-quant® D-Dimer Test System | Predicate Device |
|---|---|---|
| Intended use | For the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers. | For the quantitative determination of D-dimer by the sandwich technique, also known as enzyme-linked immunosorbent assay (ELISA). |
| Indication for use | Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation. | Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation. |
| Sample type | plasma | Plasma |
| Sample tubes | Citrate | Citrate |

# 510(k) Summary, continued

**Substantial equivalence - differences**

The following table compares the Tina-quant D-Dimer Test System with the predicate device.

| Feature | Tina-Quant® D-Dimer Test System | Predicate Device |
|---|---|---|
| Assay protocol | Immuno-turbidimetric assay | ELISA (enzyme-linked immunosorbent assay) |
| Traceability / Standardization | Standardized against Asserachrom D-Dimer method | Not shown in package insert |
| Measuring range | 0.15 – 9.0 µg/ml | NA |

**Substantial equivalence – performance characteristics**

The performance characteristics of the Tina-quant® D-Dimer and the predicate device are compared in the table below.

| Feature | Tina-quant® D-Dimer Test System | Predicate Device |
|---|---|---|
| With-in run precision (%CV) | Plasma<br>7.3% @ 0.19 µg /ml<br>Controls<br>1.7% @ 0.86 µg /ml<br>0.8% @ 5.11 µg /ml | Plasma<br>3.37% @ 0.1382 µg/ml<br>4.79% @ 0.9271 µg/ml. |
| Inter-assay precision (%CV) | Between Day:<br>Plasma<br>6.5% @ 0.30 µg /ml<br>Controls<br>8.3% @ 0.87 µg /ml<br>3.2% @ 4.58 µg /ml | Plasma<br>2.06% @ 0.1348 µg/ml<br>4.18% @ 0.5238 µg/ml |
| Analytical sensitivity | 0.04 µg /ml | 0.005 µg/ml |
| Method Comparison | Hitachi 717 (Y) vs Asserachrom D-Di Kit (X)<br>Bablok-Passing<br>Y= 1.03x – 0.11 µg /ml<br>r= 0.775<br>Hitachi 911(Y) vs Organon Teknika Fibrinostika FBDP MicroELISA Reader (X)<br>Y=0.9976x + 0.300 µg/ml<br>r=0.975 | NA |
| Calibration frequency | • Each lot<br>• As required by QC procedure | • Each run |

| Feature | Tina-Quant® D-Dimer | Predicate Device |
|---|---|---|
| Limitations | • No significant interference from conjugated or unconjugated bilirubin up to an I index of 20.<br>• No significant interference from hemoglobin up to an H index of 500.<br>• No significant interference from lipemia up to an L index of 750.<br>• No significant interference from rheumatoid factors up to 100 IU/ml.<br>• High concentrations of D-fragments can lead to depressed measurements.<br>• High levels of IgM can lead to increased measurements. | • Presence of anti-mouse antibodies leads to aberrant results. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 6 2001

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K002706
Trade Name: Roche Diagnostics Tina-quant® D-Dimer Test System
Regulatory Class: II Product Code: DAP
II GHH
Dated: February 9, 2001
Received: February 13, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): N/A

Device Name: Roche Diagnostic Tina-Quant® D-Dimer

Indications For Use:

For the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers. Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intravascular coagulation.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)